IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC., Defendants.	)	Case No. 1:14-cv-99-IMK

DECLARATION OF WILLIAM O. ADAMS IN SUPPORT OF DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S RESPONSE TO GILEAD'S MOTION TO DEFER CONSIDERATION OF MYLAN'S INDEFINITENESS ARGUMENT OR, ALTERNATIVELY, FOR LEAVE TO FILE A REPLY

I, William O. Adams, do hereby declare as follows:

1. I make this declaration in support of the Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.'s (collectively, "Mylan") Response to Gilead's Motion to Defer Consideration of Mylan's Indefiniteness Argument or, Alternatively, for Leave to File a Reply. I am a partner in the law firm of Knobbe, Martens, Olson & Bear, LLP and I am admitted to practice *pro hac vice* in this Court. I am one of the attorneys representing Mylan in this matter and unless otherwise stated, I could and would testify competently thereto.

2. Mylan raised its indefiniteness argument during the meet-and-confer process after seeing Gilead's proposed constructions.

3. In fact, during the meet-and-confer process the parties never discussed whether part of the preamble should be non-limiting.

4. Although the parties agreed during Markman briefing that the "chemically stable" portion of the preamble is non-limiting, that does not change the fact that Gilead failed to indicate during the meet-and-confer process that it intended to treat half of the preamble as limiting and half as non-limiting.

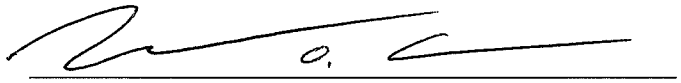
5. Attached hereto as Exhibit 1 is a true and correct copy of Plaintiffs' List of Claim Terms to be Disputed and Proposed Claim Construction of Terms, dated January 26, 2015.

6. Attached hereto as Exhibit 2 is a true and correct copy of an email from T. Krzeminski to D. Bassett, dated February 9, 2015.

7. Attached hereto as Exhibit 3 is a true and correct copy of an email from V. Ferrera to T. Krzeminski, dated February 10, 2015.

I swear under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed at Irvine, California on March 26, 2015.



William O. Adams

CERTIFICATE OF SERVICE

I hereby certify that on March 26, 2015, I filed the foregoing DECLARATION OF WILLIAM O. ADAMS IN SUPPORT OF DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S RESPONSE TO GILEAD'S MOTION TO DEFER CONSIDERATION OF MYLAN'S INDEFINITENESS ARGUMENT OR, ALTERNATIVELY, FOR LEAVE TO FILE A REPLY with the Clerk of the Court using the CM/ECF system, which will send a notice of electronic filing to the attorneys of record for Plaintiffs Gilead Sciences, Inc. and Emory University.

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20118789

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No. 1:14-cv-99 (IMK)

PLAINTIFFS' LIST OF CLAIM TERMS TO BE DISPUTED
AND PROPOSED CLAIM CONSTRUCTION OF TERMS

Pursuant to the Court's October 6, 2014 Scheduling Order (Dkt. 53) and December 5, 2014 Order Amending the Scheduling Order (Dkt. 77), Plaintiffs Gilead Sciences, Inc. and Emory University (collectively, "Plaintiffs") hereby identify the claim terms of U.S. Patent Nos. 6,642,245 ("the '245 Patent"), 6,703,396 ("the '396 Patent"), 8,592,397 ("the '397 Patent"), and 8,716,264 ("the '264 Patent") that are in dispute and proposed constructions of those terms.

As set forth in Plaintiffs' Objections and Response to Defendants' First Set of Interrogatories (Nos. 1-10), Plaintiffs are currently asserting Claim 6 of the '245 Patent; Claims 1, 3-5, 13, 15, and 16 of the '396 Patent; Claims 1-6, 14-16, 19-22, and 24-26 of the '397 Patent; and Claims 1-3, 9-17, 25, 33, and 34 of the '264 Patent (collectively, "the Asserted Claims") against Defendants Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Defendants"). The claim terms and proposed constructions disclosed herein relate only to the currently Asserted Claims.

I. '245 Patent

Based on the information presently available to Plaintiffs, Plaintiffs do not believe that any of the terms of the currently Asserted Claim of the '245 Patent require construction by the Court.

II. '396 Patent

Based on the information presently available to Plaintiffs, Plaintiffs do not believe that any of the terms of the currently Asserted Claims of the '396 Patent require construction by the Court.

III. '397 Patent

Claim Term	Asserted Claim	Proposed Construction
"chemically stable fixed dose combination"	1-6, 14-16, 19-22, 24-26	a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient in which a first component (such as FTC) of the mixture does not substantially degrade a second component (such as TDF) when the two are physically combined in such a unit dosage formulation
"degradation"	1-6, 14-16, 19-22, 24-26	loss in % label strength

III. '264 Patent

Claim Term	Asserted Claim	Proposed Construction
"chemically stable fixed dose combination"	1-3, 9-17, 25, 33, 34	a unit dosage formulation comprising a fixed amount of each active pharmaceutical ingredient in which a first component (such as FTC) of the mixture does not substantially degrade a second component (such as TDF) when the two are physically combined in such a unit dosage formulation

"degradation"	1-3, 9-17, 25, 33, 34	loss in % label strength
40° C./70% relative humidity	1-3, 9, 16, 17, 25, 33, 34	40° C./75% relative humidity

This disclosure is based upon information and documents currently available to and located by Plaintiffs and their attorneys. Plaintiffs' investigation is ongoing, and discovery in this action is ongoing. Plaintiffs reserve the right to amend, modify and/or supplement this disclosure as appropriate to address (i) any terms or claim construction positions proposed by Defendants, (ii) any discovery, including prior art, or (iii) any other relevant developments in this action, including but not limited to additional non-infringement or invalidity arguments that Defendants may assert. Plaintiffs further note that their identification of any term or phrase in this disclosure is not an admission that the term or phrase requires construction, and hereby reserve the right not to propose a construction for any identified term or phrase.

Dated: January 26, 2015

Respectfully submitted,

/s/ David B. Bassett

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Attorneys for Plaintiffs Gilead Sciences, Inc. and Emory University

EXHIBIT 2

From: Thomas.Krzeminski
Sent: Monday, February 09, 2015 3:17 PM
To: Bassett, David
Cc: 2tpk; Bill.Zimmerman; Jay.Deshmukh
Subject: RE: Gilead v. Mylan: Follow-Up on Claim Construction Meet & Confer

Dave,

I write regarding the parties' ongoing claim construction discussions. Below I summarize Mylan's positions on the points raised in your email to me of February 5. To the extent your email did not include certain claim terms that we discussed during the meet and confer, I have also summarized our position here, to avoid any confusion regarding what claim terms are presently in dispute:

"chemically stable fixed dose combination": Please let us know if you agree to construe the "fixed dose combination" component of this term as "a unit dosage form containing a fixed amount of each active pharmaceutical ingredient." Accordingly, we believe that the entire phrase "chemically stable fixed dose combination" is properly construed as "a unit dosage form containing a fixed amount of each active pharmaceutical ingredient, where one active pharmaceutical ingredient does not cause degradation of another active pharmaceutical ingredient." In its initial Proposed Claim Constructions, Gilead's construction of this claim term improperly construes "chemically stable" as ". . . does not ***substantially*** degrade . . ." As I informed you during our meet and confer, we disagree with Gilead's construction. Your email below does not specify whether Gilead has dropped this construction of "chemically stable," instead saying only that Gilead believes that the phrase "chemically stable" does not need to be construed by the Court. Assuming Gilead still construes the phrase "chemically stable" to mean "does not substantially degrade," Mylan disagrees with Gilead's construction and will brief the issue during claim construction.

"pharmaceutical dosage form": Please let us know if Gilead will agree to construe this term as "a pharmaceutical dosage form for human administration."

"dosage form is oral": Please let us know if Gilead will agree to construe this term as "an oral dosage form for human administration."

"less than x% degradation of the [TDF] or [FTC] after 6 months": In view of our call, we agree to drop the "but not including" portion of Mylan's proposed construction. Please let us know if Gilead will agree to construe this term as "less than x% degradation of either TDF or FTC after 6 months." If not, we intend to brief the issue.

"less than x% degradation of [TDF] over a 24-hour period": In view of our call, we agree to drop the "but not including" portion of Mylan's proposed construction. Please let us know if Gilead will agree to construe this term as "less than x% degradation of [TDF] over any 24-hour period." During our meet and confer last week, we discussed whether under Mylan's proposed construction the claimed "24-hour period" should be construed to occur within the shelf life of the product. We are willing to discuss such a compromise, if Gilead otherwise agrees to Mylan's construction. If not, we intend to brief the issue.

"treatment of the symptoms or effects of an HIV infection": Mylan construes this term as "treatment of the symptoms or effects of an HIV infection to any extent." We believe we are at an impasse, and intend to brief this issue.

"degradation": Mylan agrees to construe "degradation" as "loss in % label strength."

"less than x% degradation of [TDF] and [FTC] after 6 months": In view of our call, we agree to drop the "but not including" portion of Mylan's proposed construction. Please let us know if Gilead will agree to construe this term as "less than x% degradation of each of [TDF] and [FTC] after 6 months." If not, we intend to brief the issue.

"40 degrees C./70% relative humidity": We do not believe that this term needs to be construed.

Also, this confirms that Gilead has dropped claim 25 of the '264 patent from its infringement allegations.

Please let us know if you would like to continue discussing any of the foregoing claim terms. We reserve the right to revert to any or all of our original claim construction positions, if Gilead refuses to accept our offers to compromise.

Regards,
Tom

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From: Bassett, David [mailto:David.Bassett@wilmerhale.com]
Sent: Thursday, February 05, 2015 3:19 PM
To: Thomas.Krzeminski
Subject: Gilead v. Mylan: Follow-Up on Claim Construction Meet & Confer

Tom:

As a follow up to our helpful meet & confer on Tuesday, I am writing to see if we can further narrow the claim construction disputes that need to be presented to the Court. I know you and I agreed to have a further discussion on this topic early next week, but given that our claim construction brief is due two weeks from today, I am sure you can appreciate why we would prefer to come to any agreements sooner rather than later. Having said that, please note that our primary client contact is out of the country, and we have not yet been able to discuss these proposals with him, so we must reserve our right to amend our proposals once we have been able to speak with our client. Likewise, we are offering these proposals as a potential compromises, and therefore reserve our right to revert to any or all of our original positions if Mylan does not accept our proposed compromises.

"[chemically stable] fixed dose combination": As we discussed on Tuesday, we cannot accept Mylan's proposed construction of this term because, among other things, it appears to us to read "fixed dose" out of the claim entirely and would arguably require that there be no degradation whatsoever, which is plainly contrary to the remaining claim language, the specifications, and the file histories of the patents. To avoid the need to brief that dispute, however, we would propose that the parties agree that "chemically stable" does not need to be construed by the Court (not least of which, because the "wherein" clauses of the claims define more specifically the claimed stability required in each claim), and instead construe only "fixed dose combination." Our proposed construction for that term is: "a unit dosage formulation comprising a fixed amount of each active pharmaceutical agreement."

"pharmaceutical dosage form": As we discussed on Tuesday, we cannot accept Mylan's proposed "e.g." listing as part of a proper claim construction. If that listing is removed, the remainder of Mylan's proposed construction reads "Any pharmaceutical dosage form available for human administration." We cannot agree to the word "any" – that is simply

reading a word into the claim term. And the word "available" is not supported by the specification. The word "suitable," however, is: see, e.g., the '567 patent, Col. 14:12-15. Therefore, we would be willing to agree to the construction: "A pharmaceutical dosage form suitable for human administration." To avoid the need to fight over "any" versus "a," we would further be willing to agree that we will not rely on the claim term "pharmaceutical dosage form," standing alone, to limit the scope of the claims beyond the agreed construction that it be "suitable for human administration." (To be absolutely clear, we of course would not be waiving any right to argue that any claim as a whole is limited to certain dosage forms.)

"less than X% degradation of the [TDF] or [FTC] after 6 months": for the reasons we discussed on Tuesday, we cannot agree to Mylan's proposal to add "beginning at any point in time" to the construction of this claim term. If Mylan will agree to drop that part of its proposed construction, that leaves "less than, but not including, X% degradation of either the [TDF] or [FTC] after the passage of 6 months." The only words this remaining proposed construction adds to the actual claim language is "but not including," which is redundant of "less than," and "the passage of," which adds nothing of meaning to "after 6 months." So we would propose that the parties agree that this claim term does not need to be construed by the Court.

"dosage form is oral": Again, we cannot agree to the "e.g." listing included in Mylan's proposed construction. With that removed, we think "dosage form is oral" need not be construed by the Court. If Mylan agrees, we would further be willing to agree that we will not rely on the claim term "dosage form is oral," standing alone, to limit the scope of the claims beyond the requirement that the dosage form be suitable to be taken orally. (Again, to be absolutely clear, we would not be waiving any right to argue that any claim as a whole is limited to certain oral dosage forms.)

"less than X% degradation of [TDF] over a 24 hour period": We literally do not understand the meaning of the language in Mylan's proposed construction "beginning at any point in time." Any 24 hour period between now and the end of time? Every single 24 hour period? We think this language adds ambiguity to a claim term that is otherwise clear on its face. The only words the remaining proposed construction adds to the actual claim language is "but not including," which is redundant of "less than," and "the passage of," which adds nothing of meaning to "over a 12 hour period." We would propose agreeing that this claim term need not be construed by the Court.

"treatment of the symptoms of and HIV infection": As we explained on Tuesday, we believe there is no support in the specification for adding the phrase "to any extent." The claim language is clear on its face and we would propose agreeing that his claim term need not be construed by the Court.

Finally, to simplify the issues for construction, the plaintiffs are willing to drop claim 25 of the '264 patent from its list of asserted claims.

Please let me know at your early convenience whether Mylan can agree to any of these proposals for narrowing the parties' claim construction disputes.

Best regards,

Dave

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david.bassett@wilmerhale.com

Please consider the environment before printing this email.

EXHIBIT 3

From: Ferrera, Vinita [mailto:Vinita.Ferrera@wilmerhale.com]
Sent: Tuesday, February 10, 2015 9:38 AM
To: Thomas.Krzeminski; Bill.Zimmerman; Jay.Deshmukh; 2tpk
Cc: Bassett, David; Manspeizer, David A.; Saxton, Kate; ctracyjames@mayerbrown.com; Borello, Christopher (CBorello@fchs.com) (CBorello@fchs.com)
Subject: FW: Gilead v. Mylan: Follow-Up on Claim Construction Meet & Confer

Dear Tom:

Thank you for your e-mail yesterday setting forth Mylan's claim construction positions. We appreciate Mylan's willingness to attempt to narrow or resolve some of the disputes. Based on our review of your e-mail, it appears we have made some progress in that regard. However, we have some outstanding questions or concerns that need to be addressed.

"chemically stable fixed dose combination" – With respect to the "chemically stable" portion of the claim term, we continue to believe that this phrase does not need construction (or if it does, that Mylan's construction is incorrect). With respect to the "fixed dose combination" portion of the term, we note that Mylan's proposed construction differs slightly from what we had proposed. Specifically, Mylan's construction refers to a "unit dosage form containing" rather than a "unit dosage formulation comprising." The specification uses the phrase "unit dosage formulation comprising" when describing the fixed dose combination ('397 patent, col. 14:5-8), and accordingly, we think that is the appropriate construction. However, in order to determine whether it is necessary to brief this issue, it would be helpful to understand why Mylan believes that "unit dosage form containing" should be used instead.

"pharmaceutical dosage form" / "dosage form is oral" - Gilead agrees with Mylan's proposed construction of these terms as "a pharmaceutical dosage form for human administration" and "an oral dosage form for human administration."

"less than x% degradation of the [TDF] or [FTC] after 6 months" vs. ***"less than X% degradation of [TDF] and [FTC] after 6 months"*** – It remains unclear to us exactly what Mylan means by "either [TDF] or [FTC]" vs. "each of [TDF] and [FTC]" in this context. Gilead understands "or" in this context to mean that neither the TDF nor the FTC can degrade more than 10%, while "and" means that the cumulative amount of degradation of TDF and FTC is less than 10%. However, Mylan's position appears to be that if, after 6 months, there was 90% degradation of TDF, but only 5% degradation of FTC, the product would fall within the scope of claim 1 of the '397 patent. If that is the case, we cannot agree to Mylan's proposed constructions of "and" and "or," and we will plan to brief this issue.

"less than x% degradation of [TDF] over a 24-hour period" – We understand Mylan's proposed construction to be "less than X% degradation of TDF over any 24-hour period," and that Mylan is willing to consider whether the phrase should be construed to occur within the shelf life of the product. It is unclear to us whether the phrase "any 24-hour period" in Mylan's proposed construction means "every 24-hour period" or "any single 24-hour period." Assuming that it means "any single 24-hour period," then Gilead would be willing to accept the following construction: "less than X% degradation of TDF over any 24-hour period within the shelf life of the product."

"treatment of the symptoms or effects of an HIV infection" – While we do not agree with Mylan's proposed construction of this term (in particular, the "to any extent" portion of the construction), we think it behooves the parties to avoid asking the Court to construe a term upon which no issue may turn. Accordingly, before we submit this issue to the Court, it would be helpful to understand why Mylan believes that the "to any extent" aspect of its construction matters to the issues of infringement or validity.

"degradation" – the parties agree to construe this term as "loss in % label strength."

"40 degrees C./70% relative humidity" - It is unclear to us from Mylan's response whether or not Mylan is in agreement with the proposed correction to the claim language. I note that we understand the examiner has approved the certificate of correction, and the certificate is due to be published shortly. Accordingly, there should be no doubt that correction is appropriate, and it would seem to be an unnecessary expenditure of the parties' and the Court's resources to have to brief and argue this issue.

If it would be helpful to discuss these issues by telephone today or tomorrow, please let us know.

Regards,

Vinita

Begin forwarded message:

> **From:** Thomas.Krzeminski <Thomas.Krzeminski@knobbe.com>
> **Date:** February 9, 2015 at 6:17:14 PM EST
> **To:** "Bassett, David" <David.Bassett@wilmerhale.com>
> **Cc:** 2tpk <2tpk@knobbe.com>, Bill.Zimmerman <Bill.Zimmerman@knobbe.com>, Jay.Deshmukh <Jay.Deshmukh@knobbe.com>
> **Subject: RE: Gilead v. Mylan: Follow-Up on Claim Construction Meet & Confer**
>
> Dave,
>
> I write regarding the parties' ongoing claim construction discussions. Below I summarize Mylan's positions on the points raised in your email to me of February 5. To the extent your email did not include certain claim terms that we discussed during the meet and confer, I have also summarized our position here, to avoid any confusion regarding what claim terms are presently in dispute:
>
> ***"chemically stable fixed dose combination"***: Please let us know if you agree to construe the "fixed dose combination" component of this term as "a unit dosage form containing a fixed amount of each active pharmaceutical ingredient." Accordingly, we believe that the entire phrase "chemically stable fixed dose combination" is properly construed as "a unit dosage form containing a fixed amount of each active pharmaceutical ingredient, where one active pharmaceutical ingredient does not cause degradation of another active pharmaceutical ingredient." In its initial Proposed Claim Constructions, Gilead's construction of this claim term improperly construes "chemically stable" as ". . . does not ***substantially*** degrade . . ." As I informed you during our meet and confer, we disagree with Gilead's construction. Your email below does not specify whether Gilead has dropped this construction of "chemically stable," instead saying only that Gilead believes that the phrase "chemically stable" does not need to be construed by the Court. Assuming Gilead still construes the phrase "chemically stable" to mean "does not substantially degrade," Mylan disagrees with Gilead's construction and will brief the issue during claim construction.
>
> ***"pharmaceutical dosage form"***: Please let us know if Gilead will agree to construe this term as "a pharmaceutical dosage form for human administration."
>
> ***"dosage form is oral"***: Please let us know if Gilead will agree to construe this term as "an oral dosage form for human administration."

"less than x% degradation of the [TDF] or [FTC] after 6 months": In view of our call, we agree to drop the "but not including" portion of Mylan's proposed construction. Please let us know if Gilead will agree to construe this term as "less than x% degradation of either TDF or FTC after 6 months." If not, we intend to brief the issue.

"less than x% degradation of [TDF] over a 24-hour period": In view of our call, we agree to drop the "but not including" portion of Mylan's proposed construction. Please let us know if Gilead will agree to construe this term as "less than x% degradation of [TDF] over any 24-hour period." During our meet and confer last week, we discussed whether under Mylan's proposed construction the claimed "24-hour period" should be construed to occur within the shelf life of the product. We are willing to discuss such a compromise, if Gilead otherwise agrees to Mylan's construction. If not, we intend to brief the issue.

"treatment of the symptoms or effects of an HIV infection": Mylan construes this term as "treatment of the symptoms or effects of an HIV infection to any extent." We believe we are at an impasse, and intend to brief this issue.

"degradation": Mylan agrees to construe "degradation" as "loss in % label strength."

"less than x% degradation of [TDF] and [FTC] after 6 months": In view of our call, we agree to drop the "but not including" portion of Mylan's proposed construction. Please let us know if Gilead will agree to construe this term as "less than x% degradation of each of [TDF] and [FTC] after 6 months." If not, we intend to brief the issue.

"40 degrees C./70% relative humidity": We do not believe that this term needs to be construed.

Also, this confirms that Gilead has dropped claim 25 of the '264 patent from its infringement allegations.

Please let us know if you would like to continue discussing any of the foregoing claim terms. We reserve the right to revert to any or all of our original claim construction positions, if Gilead refuses to accept our offers to compromise.

Regards,
Tom

Thomas Krzeminski
Partner
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From: Bassett, David [mailto:David.Bassett@wilmerhale.com]
Sent: Thursday, February 05, 2015 3:19 PM
To: Thomas.Krzeminski
Subject: Gilead v. Mylan: Follow-Up on Claim Construction Meet & Confer

Tom:

As a follow up to our helpful meet & confer on Tuesday, I am writing to see if we can further narrow the claim construction disputes that need to be presented to the Court. I know you and I agreed to have a further discussion on this topic early next week, but given that our claim construction brief is due two weeks from today, I am sure you can appreciate why we would prefer to come to any agreements sooner rather than later. Having said that, please note that our primary client contact is out of the country, and we have not yet been able to discuss these proposals with him, so we must reserve our right to amend our proposals once we have been able to speak with our client. Likewise, we are offering these proposals as a potential compromises, and therefore reserve our right to revert to any or all of our original positions if Mylan does not accept our proposed compromises.

"[chemically stable] fixed dose combination": As we discussed on Tuesday, we cannot accept Mylan's proposed construction of this term because, among other things, it appears to us to read "fixed dose" out of the claim entirely and would arguably require that there be no degradation whatsoever, which is plainly contrary to the remaining claim language, the specifications, and the file histories of the patents. To avoid the need to brief that dispute, however, we would propose that the parties agree that "chemically stable" does not need to be construed by the Court (not least of which, because the "wherein" clauses of the claims define more specifically the claimed stability required in each claim), and instead construe only "fixed dose combination." Our proposed construction for that term is: "a unit dosage formulation comprising a fixed amount of each active pharmaceutical agreement."

"pharmaceutical dosage form": As we discussed on Tuesday, we cannot accept Mylan's proposed "e.g." listing as part of a proper claim construction. If that listing is removed, the remainder of Mylan's proposed construction reads "Any pharmaceutical dosage form available for human administration." We cannot agree to the word "any" – that is simply reading a word into the claim term. And the word "available" is not supported by the specification. The word "suitable," however, is: see, e.g., the '567 patent, Col. 14:12-15. Therefore, we would be willing to agree to the construction: "A pharmaceutical dosage form suitable for human administration." To avoid the need to fight over "any" versus "a," we would further be willing to agree that we will not rely on the claim term "pharmaceutical dosage form," standing alone, to limit the scope of the claims beyond the agreed construction that it be "suitable for human administration." (To be absolutely clear, we of course would not be waiving any right to argue that any claim as a whole is limited to certain dosage forms.)

"less than X% degradation of the [TDF] or [FTC] after 6 months": for the reasons we discussed on Tuesday, we cannot agree to Mylan's proposal to add "beginning at any point in time" to the construction of this claim term. If Mylan will agree to drop that part of its proposed construction, that leaves "less than, but not including, X% degradation of either the [TDF] or [FTC] after the passage of 6 months." The only words this remaining proposed construction adds to the actual claim language is "but not including," which is redundant of "less than," and "the passage of," which adds nothing of meaning to "after 6 months." So we would propose that the parties agree that this claim term does not need to be construed by the Court.

"dosage form is oral": Again, we cannot agree to the "e.g." listing included in Mylan's proposed construction. With that removed, we think "dosage form is oral" need not be construed by the Court. If Mylan agrees, we would further be willing to agree that we will not rely on the claim term "dosage form is oral," standing alone, to limit the scope of the claims beyond the requirement that the dosage form be suitable to be taken orally. (Again, to be absolutely clear, we would not be waiving any right to argue that any claim as a whole is limited to certain oral dosage forms.)

"less than X% degradation of [TDF] over a 24 hour period": We literally do not understand the meaning of the language in Mylan's proposed construction "beginning at any point in time." Any 24 hour period between now and the end of time? Every single 24 hour period? We think this language adds ambiguity

to a claim term that is otherwise clear on its face. The only words the remaining proposed construction adds to the actual claim language is "but not including," which is redundant of "less than," and "the passage of," which adds nothing of meaning to "over a 12 hour period." We would propose agreeing that this claim term need not be construed by the Court.

"treatment of the symptoms of and HIV infection": As we explained on Tuesday, we believe there is no support in the specification for adding the phrase "to any extent." The claim language is clear on its face and we would propose agreeing that his claim term need not be construed by the Court.

Finally, to simplify the issues for construction, the plaintiffs are willing to drop claim 25 of the '264 patent from its list of asserted claims.

Please let me know at your early convenience whether Mylan can agree to any of these proposals for narrowing the parties' claim construction disputes.

Best regards,

Dave

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